

NIKLASON et al
Appl. No. 10/074,250
May 31, 2005

REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

Claims 1 and 12 have been revised so as to be drawn to a method of treating or inhibiting progression of cerebral vasospasm that follows subarachnoid hemorrhage (SAH). Support for the revision can be found throughout the application, including at page 1, paragraph beginning at line 16, which makes it clear that cerebral vasospasm follows SAH. Further support is found in the Examples (note particularly Example II). The revision does not raise new issues but merely serves to define the invention with additional clarity.

Claims 24-27 have been cancelled without prejudice. Claims drawn to non-elected species are retained and the Examiner is urged to consider these claims in view of the comments that follow which underscore the patentability of the generic claims.

Claim 1 stands rejected under 35 USC 112, first paragraph. The rejection is traversed.

The Examiner rejects claim 1 on the basis that the disclosure allegedly "does not reasonably provide enablement for any compounds for inhibiting vascular cell proliferation" (emphasis added). The Examiner makes reference to the eight Wands factors but in considering the factor relating to the amount of direction or guidance presented, the Examiner relies on Univ. Calif v. Eli Lilly to support the rejection. Respectfully, this reliance is misplaced.

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In contrast to the situation at hand, the issue in Lilly was written description, not enablement. Thus the relevance of the Examiner's comments is not seen.

If the Examiner intended a rejection based on lack of written description
rather than lack of enablement, he/she is requested to so indicate in a new non-final
Action so that Applicants will have the opportunity to respond to which they are
entitled.

As regards the Examiner's assertion that the language of claim 1 is functional at the point of novelty (this assertion being based on Lilly), Applicants strongly disagree.

As pointed out previously, the present claims are drawn to a method of treating or inhibiting progression of cerebral vasospasm. The novelty of the claimed methods results not from the specific nature of the agent used but rather from the fact that Applicants were the first to appreciate and disclose that narrowing of cerebral arteries that is characteristic of cerebral vasospasm is in fact due to proliferation of cells in the vascular wall and/or accumulation of extracellular matrix under the influence of growth factors.

Applicants do not contend that all agents suitable for use in the claimed method are novel. On the contrary, the subject specification is replete with examples of known agents can be used in Applicants' novel methods. At pages 7-10 of the application, a large number and wide variety of suitable agents are described. (Applicants also provide, at pages 10-12 of the application, methods of identifying yet further agents that would be suitable for use in the invention.)

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As pointed out above, the present rejection is based on a lack of enablement, not a lack of written description (despite the Examiner's reliance on Lilly). While not intending to respond to a rejection that has not formally been made (lack of written description), the Examiner's attention is directed to the fact that the claims in Lilly were drawn to a product (cDNA) not a method. The product was a vertebrate insulin cDNA or mammalian insulin cDNA. The Lilly court found these recitations provided an inadequate written description of the genus because they did not distinguish the claimed genus from others, except by function. This is clearly a different situation than that which exists here.

In re Angstadt and Griffin, 190 USPQ 214 (CCPA 1976) is an enablement case and thus far more relevant to the present rejection of claim 1. In Angstadt, the court acknowledged that Appellants had not disclosed every catalyst that would work in the claimed chemical process and addressed the question of whether, in an unpredictable art, the enablement requirement of 35 USC 112, first paragraph, requires disclosure of every species encompassed by the claims. The court found that there was not such requirement, pointing out that:

"such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed."

The court concluded that, having decided that disclosure of every species encompassed by the claims is not required, even an unpredictable art, each case must be

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determined on its own facts. In Angstadt, the court found that Appellants' disclosure of a list of catalysts and details of how to make and use them to be sufficient. The court pointed out that the experimentation required to determine which species would work would not be undue and would certainly not "require ingenuity beyond that to be expected of one of ordinary skill in the art" (citing Fields v. Conover, 170 USPQ 276, 279 (CCPA 1971)).

The facts in Angstadt are similar to those here. Here, the disclosure at pages 7-10 includes numerous types of agents suitable for use in the invention, as well as numerous examples of specific agents. Also included are citations for publications teaching additional specific agents (which publications are incorporated by reference at page 28). In addition, the application includes at pages 10-12 examples of methods that can be used to screen for suitable agents. Clearly, given the holding in Angstadt, nothing more should be required of Applicants.

The drug-drug interactions to which the Examiner refers are ones well known and commonly addressed by those skilled in the relevant art.

In view of the above, it will be clear that the reject based on lack of enablement is not well founded. Reconsideration is requested.

Claims 1, 10 and 11 stand rejected under 35 USC 102(b) as allegedly being anticipated by Black. Withdrawal of the rejection is submitted to be in order in view of the above-noted claim revisions and comments that follow.

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Black et al relates to "a method for selectively opening abnormal brain tissue capillaries ... to allow selective passage of ... neuropharmaceutical agents into abnormal tissue." Subarachnoid hemorrhage (SAH) is indicated as being an example of a specific type of abnormal brain tissue. (See paragraph bridging columns 3 and 4 of Black.)

Cerebral vasospasm is a complication of SAH that generally has peak clinical manifestations at 7-10 days following SAH. The syndrome is characterized by diffuse narrowing of cerebral arteries in the general region of the SAH. The present invention relates to methods of treating, or inhibiting progression of, this complication/syndrome which, left unaddressed, can become so severe that blood flow to previously undamaged brain is compromised, resulting in risk of subsequent stroke.

While Black et al makes reference to SAH as a specific type of abnormal brain tissue to which his method is applicable, the citation would in no way have suggested the presently claimed approach to treating, or inhibiting progression of, the cerebral vasospasm following SAH that Applicants have realized is due to the proliferation of cells in the vascular wall and/or accumulation of extracellular matrix. Accordingly, Black et al does not teach Applicants' claimed invention, nor would it have rendered that invention obvious.

Reconsideration is requested.

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This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: Mary J. Wilson
Mary J. Wilson
Reg. No. 32,955

MJW:tat
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100